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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/026,736	03/05/1993	MARC ALIZON	3495.0010-12	5247

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EXAMINER	
PARKIN, JEFFREY S	

ART UNIT	PAPER NUMBER
1648	37

DATE MAILED: 04/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/026,736	Applicant(s) ALIZON ET AL.	
	Examiner Jeffrey S. Parkin, Ph.D.	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *03* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,15,17 and 19-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11, 15, 17, and 19-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Office Action

Status of the Claims

During a telephonic interview with Salvatore J. Arrigo (Reg. No. 46,063) on 22 December, 2003, applicants' representative requested that a supplemental Office action that thoroughly considers the reply dated 23 April, 2003, be provided. Accordingly, the following supplemental Office action is set forth. Claims 11, 15, 17, and 19-35 are pending in the instant application.

35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

As previously set forth, claims 11, 17, 20-23, and 28-31 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). The claims are directed toward **purified antibodies** that bind to an HIV-1 antigen (e.g., ORF-Q, ORF-R, ORF-1, or ORF-4). Applicants' arguments have been carefully considered but are not deemed to be persuasive.

In order to satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably

conclude that the inventor had possession of the claimed invention. See, e.g., *Vas-Cath, Inc., v. Mahurkar*, 935 F.2d at 1563, 19 U.S.P.Q.2d at 1116. **The issue raised in this application is whether the original application provides adequate support for the expression and purification of the identified viral proteins, as well as, the purified antibodies directed thereto.** An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997). The claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the biomolecule of interest. *In re Bell*, 991 F.2d 781, 26 U.S.P.Q.2d 1529 (Fed. Cir. 1993). *In re Deuel*, 51 F.3d 1552, 34 U.S.P.Q.2d 1210 (Fed. Cir. 1995). A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 U.S.P.Q.2d 1895, 1905 (Fed. Cir. 1995). The court noted in this decision that a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not reasonably lead those skilled in the art to any particular species.

An applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. For some biomolecules, examples of identifying characteristics include a nucleotide or amino acid sequence, chemical structure, binding affinity, binding specificity, and molecular weight. The written description requirement may be satisfied through disclosure of function and minimal structure when there is a well-established correlation between structure and function. Without such a correlation, the capability to recognize or understand the structure form the mere recitation of function and minimal structure is highly unlikely. In the latter case, disclosure of function alone is little more than a wish for possession; it does not satisfy the written description requirement. *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566, 43 U.S.P.Q.2d 1398, 1404, 1406 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998). *In re Wilder*, 736 F.2d 1516, 1521, 222 U.S.P.Q. 369, 372-3 (Fed. Cir. 1984). Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention.

The disclosure describes the isolation and characterization of a novel HIV-1 (originally termed the lymphadenopathy-associated virus or retrovirus) proviral molecular clone. The complete nucleotide sequence of this clone was ascertained and potential open reading frames identified. Under the summary of the invention it was stated that the present invention is directed toward "providing polypeptides containing sequences in common with polypeptides encoded by the LAV genomic RNA", to provide a "means for the detection of proteins related to LAV virus ... or, to the contrary, for the detection of antibodies against the LAV virus or proteins related therewith", and "providing immunogenic polypeptides". Under a detailed description of preferred embodiments the cloning strategy was provided, the complete nucleotide sequence of the clone was set forth, and the **putative** open reading frames gag, pol, env, ORF-Q, ORF-R, and ORFs-1-5 identified. While the disclosure mentions that these polypeptides can be utilized in the production of antibodies, **there is no indication anywhere that the regions identified correspond to *bona fide* viral open reading frames.** The mere identification of a putative open reading frame in a novel virus does not demonstrate that said ORF is actually expressed during the viral lifecyle. Demonstration of a *bona fide* ORF requires the preparation of specific immunological reagents and a demonstration that the protein of interest is actually present in virions or virally infected cells. However, **perusal of the disclosure fails to suggest that applicants expressed and purified the antigens of interest.** Moreover, **there is no indication that applicants actually prepared any specific immunological reagents directed against these antigens.** The disclosure **fails** to describe the isolation and characterization of a single polyclonal or monoclonal preparation that is directed against one of these antigens. Thus, the skilled artisan would reasonably conclude that applicants were not in possession of the claimed invention at the

time of filing and that the rejection is proper.

Applicants traverse and submit that the Examiner has applied inappropriate legal criteria in making the rejection. Applicants rely upon a number of legal decisions (e.g., *Gould v. Quigg, Pfaff v. Wells Electronics Inc.*) asserting that a working embodiment is not required to meet the written description requirement. It was further argued that the claimed invention is fully enabled since the disclosure teaches the claimed polypeptides and provides art-recognized methods for producing antibodies from said polypeptides. Additional arguments suggest that the Examiner's position is inconsistent with the written description guidelines provided by the agency. Finally, applicants contend that the Examiner has failed to provide a *prima facie* case for the rejection.

Applicants' arguments have been carefully considered but are not deemed to be persuasive for the reasons of record clearly set forth *supra* and as further elaborated in the following response. First, contrary to applicants' assertions, the Examiner has applied the proper legal criteria in formulating the written description rejection and clearly set forth a *prima facie* case for a lack of written description. The legal basis for the rejection was explicitly set forth and the analysis performed consistent with Office policy. See M.P.E.P. § 2163. The first paragraph of 35 U.S.C. § 112 requires the following: (1) A **written description** of the invention; (2) The manner and process of making and using the invention (the **enablement** requirement); and (3) The **best mode** contemplated by the inventor of carrying out his invention. The written description requirement is separate and distinct from the enablement requirement. In re Barker, 559 F.2d 588, 194 U.S.P.Q. 470 (C.C.P.A. 1977), cert. denied, 434 U.S. 1064 (1978); *Vas-Cath, Inc. v. Mahurkar,* 935 F.2d 1555, 1562, 19 U.S.P.Q.2d 1111, 1115 (Fed. Cir. 1991). As previously set forth, the crux of this

rejection is not based upon enablement considerations, but whether or not the skilled artisan, upon perusal of the specification, would reasonably conclude that applicants were in possession of the claimed invention at the time of filing.

Applicants are reminded that possession of the claimed invention may be shown in many ways. For example, possession may be shown by describing an **actual reduction to practice** of the claimed invention. Possession may also be shown by a **clear depiction** of the invention in **detailed drawings** or in **structural chemical formulas** which permit a person skilled in the art to clearly recognize that applicant had possession of the claimed invention. An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention. See, e.g., *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323, 56 U.S.P.Q.2d 1481, 1483 (Fed. Cir. 2000) (the written description "inquiry is a factual one and must be assessed on a case-by-case basis"); see also *Pfaff v. Wells Electronics*, Inc., 55 U.S. at 66, 119 S.Ct. at 311, 48 U.S.P.Q.2d at 1646 ("**The word invention' must refer to a concept that is complete, rather than merely one that is substantially complete.**' It is true that reduction to practice ordinarily provides the best evidence that an invention is complete.

A specification may describe an actual reduction to practice by showing that the inventor constructed an embodiment or performed a process that met all the limitations of the claim and determined that the invention would work for its intended purpose. *Cooper v. Goldfarb*, 154 F.3d 1321, 1327, 47 U.S.P.Q.2d 1896, 1901 (Fed. Cir. 1998). See alsc *UMC Elecs. Co. v. United States*, 816 F.2d 647, 652, 2 U.S.P.Q.2d 1465, 1468 (Fed. Cir. 1987) ("[T]here cannot be a reduction to practice of the invention * * * without a physical

embodiment which includes all limitations of the claim."); *Estee Lauder Inc. v. L'Oreal, S.A.*, 129 F.3d 588, 593, 44 U.S.P.Q.2d 1610, 1614 (Fed. Cir. 1997) ("[A] reduction to practice does not occur until the inventor has determined that the invention will work for its intended purpose."); *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1578, 38 U.S.P.Q.2d 1288, 1291 (Fed. Cir. 1996) (determining that the invention will work for its intended purpose may require testing depending on the character of the invention and the problem it solves). Description of an actual reduction to practice of a biological material may be shown by specifically describing a deposit made in accordance with the requirements of 37 C.F.R. § 1.801 *et seq.* See especially 37 C.F.R. § 1.804 and § 1.809.

An applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. See, e.g., *Vas-Cath*, 935 F.2d at 1565, 19 U.S.P.Q.2d at 1118 ("drawings alone may provide a written description' of an invention as required by Sec. 112\"); *In re Wolfensperger*, 302 F.2d 950, 133 U.S.P.Q. 537 (C.C.P.A. 1962) (the drawings of applicant's specification provided sufficient written descriptive support for the claim limitation at issue); *Autogiro Co. of America v. United States*, 384 F.2d 391, 398, 155 U.S.P.Q. 697, 703 (Ct. Cl. 1967) ("In those instances where a visual representation can flesh out words, drawings may be used in the same manner and with the same limitations as the specification."); *Eli Lilly*, 119 F.3d at 1568, 43 U.S.P.Q.2d at 1406 ("In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed

genus."). The description need only describe in detail that which is new or not conventional. See *Hybritech v. Monoclonal Antibodies*, 802 F.2d at 1384, 231 U.S.P.Q. at 94; *Fonar Corp. v. General Electric Co.*, 107 F.3d at 1549, 41 U.S.P.Q.2d at 1805 (source code description not required). This is equally true whether the claimed invention is directed to a product or a process.

An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. For example, the presence of a restriction enzyme map of a gene may be relevant to a statement that the gene has been isolated. One skilled in the art may be able to determine whether the gene disclosed is the same as or different from a gene isolated by another by comparing the restriction enzyme maps. In contrast, evidence that the gene could be digested with a nuclease would not normally represent a relevant characteristic since any gene would be digested with a nuclease. Similarly, isolation of an mRNA and its **expression** to produce the protein of interest is strong evidence of possession of an mRNA for the protein.

For some biomolecules, examples of identifying characteristics include a sequence, structure, binding affinity, binding specificity, molecular weight, and length. Although structural formulas provide a convenient method of demonstrating possession of specific molecules, other identifying characteristics or combinations of characteristics may demonstrate the requisite possession. For example, unique cleavage by particular enzymes, isoelectric points of fragments, detailed restriction enzyme maps, a comparison of enzymatic activities, or antibody cross-reactivity

may be sufficient to show possession of the claimed invention to one of skill in the art. See *Lockwood*, 107 F.3d at 1572, 41 U.S.P.Q.2d at 1966 ("written description" requirement may be satisfied by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention"). A definition by function alone "does not suffice" to sufficiently describe a coding sequence "because it is only an indication of what the gene does, rather than what it is." *Eli Lilly*, 119 F.3 at 1568, 43 U.S.P.Q.2d at 1406. See also *Fiers*, 984 F.2d at 1169-71, 25 U.S.P.Q.2d at 1605-06 (discussing *Amgen Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991)).

As previously set forth, the disclosure describes the isolation and characterization of a novel HIV-1 (originally termed the lymphadenopathy-associated virus or retrovirus) proviral molecular clone. The complete nucleotide sequence of this clone was ascertained and **potential** open reading frames identified. It was not readily manifest at the time of filing if the identified open reading frames corresponded to *bonafide* viral gene products. Under the summary of the invention it was stated that the present invention is directed toward "providing polypeptides containing sequences in common with polypeptides encoded by the LAV genomic RNA", to provide a "means for the detection of proteins related to LAV virus ... or, to the contrary, for the detection of antibodies against the LAV virus or proteins related therewith", and "providing immunogenic polypeptides". Under a detailed description of preferred embodiments the cloning strategy was provided, the complete nucleotide sequence of the clone was set forth, and the **putative** open reading frames gag, pol, env, **ORF-Q**, **ORF-R**, and **ORFs-1-5** identified. While the disclosure mentions that these polypeptides can be utilized in the production of antibodies, **there is no indication anywhere that the regions identified correspond to**

***bona fide* viral open reading frames.** The mere identification of a putative open reading frame in a novel virus does not demonstrate that said ORF is actually expressed during the viral lifecyle. Demonstration of a *bona fide* ORF requires the preparation of specific immunological reagents and a demonstration that the protein of interest is actually present in virions or virally infected cells. However, **perusal of the disclosure fails to suggest that applicants expressed and purified the antigens of interest.** Moreover, **there is no indication that applicants actually prepared any specific polyclonal or monoclonal immunological reagents directed against these antigens. The disclosure fails to describe the isolation and characterization of a single polyclonal or monoclonal preparation that is directed against one of these antigens. The disclosure fails to provide deposited hybridomas. The disclosure fails to provide any details pertaining to the isotype and affinity of any given antibody.** Thus, the skilled artisan would reasonably conclude that applicants were not in possession of the claimed invention at the time of filing and that the rejection is proper. Applicants are reminded that as the Supreme Court has cautioned, **"a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."** *Brenner* v. *Manson*, 383 U.S. 519, 536 [148 U.S.P.Q. 689] (1966). Here, the inventors have identified and cloned a novel human immunodeficiency virus. However, **they have not performed any virological, biochemical, or immunological studies pertaining to the putative ORFs of interest and antibodies specific thereto.**

Applicants reliance on *Pfaff* is not particularly germane to the facts in the instant application. The *Pfaff* decision dealt with 102(b) "on sale" issues involving a computer chip socket. Perhaps more relevant to the facts in this situation is the *Hybritech*

decision. The question of reduction to practice arose and the inventors testified and provided direct evidence that monoclonal antibodies were clearly developed prior to the date in question. The inventors demonstrated unambiguously that antigens were purchased from outside sources and purified before being injected into mice; the spleen cells from those mice were fused with myelomas; the resultant hybridomas were separated into well plates for development; and a radioimmunoassay procedure was carried out to determine the affinity of the antibodies. Interestingly enough, the inventors of the instant application have been unable to demonstrate at the time of filing that they expressed and purified the viral antigens of interest, that said purified antigens were used to immunize mice and generate polyclonal and monoclonal reagents, that said immunological reagents were of the desired specificity and affinity, and that said immunological reagents were useful in detecting the viral antigens in biological samples. Applicants are obviously trying to capture subject matter to which they are clearly not entitled.

The reliance on Example 16 in the written description guidelines is also insufficient to remedy the deficiencies in the specification. First, applicants are reminded that the guidelines do not constitute substantive rulemaking and hence do not have the force and effect of law. They are intended to provide guidance to the examining corps when evaluating whether or not the application meets the written description requirement. Second, the inquiry into whether the description requirement is met is a question of fact that must be determined on a case-by-case basis. Thus, generic examples provided by in the guidelines should be interpreted carefully. The referenced example has several critical differences as compared to the instant application. Example 16 states that the "specification teaches that **antigen X has been isolated** and is **useful for detection of HIV infections.** The

specification teaches **antigen X as purified by gel filtration** and provides **characterization of the antigen** as having a molecular weight of 55 KD. The specification also **provides a clear protocol by which antigen X was isolated.**" The instant specification is silent concerning all of these facts. The disclosure does **not** describe the isolation and purification of any of the claimed antigens. The disclosure does **not** describe detailed methodologies of purifying the antigens of interest. The disclosure does **not** describe the utilization of the claimed antigens for the detection of LAV infection. The disclosure does **not** describe the preparation of polyclonal or monoclonal immunological reagents. The disclosure does **not** describe detailed protocols for preparing such reagents. The disclosure does **not** describe the isolation, purification, and characterization of any immunological reagents. The disclosure does **not** demonstrate that said reagents would be useful in the detection of HIV infection. The problem with the claimed invention, as previously set forth, is that applicants have only identified putative open reading frames based upon the nucleotide sequence of the cDNA. Simply identifying said putative ORFs does not prove that they are bonafide open reading frames. This can only be determined by isolating and purifying the antigens of interest, generating immunological reagents to said antigens, and performing the appropriate immunological assay to demonstrate that said antigens are expressed in the context of a viral infection (i.e., in the virion or infected cell). Accordingly, the rejection has been properly set forth and is maintained.

Claims 15, 19, 24-27, and 32-35 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323

(C.C.P.A. 1981). *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). The claims are directed toward **purified immunological complexes** comprising an HIV-1 antigen (e.g., ORF-Q, ORF-R, ORF-1, or ORF-4) and an antibody (polyclonal/monoclonal (claim 15) or monoclonal (claim 19)) that binds to said antigen. Applicants' arguments have been carefully considered but not deemed to be persuasive.

As previously set forth, in order to satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Vas-Cath, Inc., v. Mahurkar*, 935 F.2d at 1563, 19 U.S.P.Q.2d at 1116. The issue raised in this application is whether the original application provides adequate support for the claimed purified immunological complexes. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997). The claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the biomolecule of interest. *In re Bell*, 991 F.2d 781, 26 U.S.P.Q.2d 1529 (Fed. Cir. 1993). *In re Deuel*, 51 F.3d 1552, 34 U.S.P.Q.2d 1210 (Fed. Cir.

1995). A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 U.S.P.Q.2d 1895, 1905 (Fed. Cir. 1995). The court noted in this decision that a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not reasonably lead those skilled in the art to any particular species.

An applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. For some biomolecules, examples of identifying characteristics include a nucleotide or amino acid sequence, chemical structure, binding affinity, binding specificity, and molecular weight. The written description requirement may be satisfied through disclosure of function and minimal structure when there is a well-established correlation between structure and function. Without such a correlation, the capability to recognize or understand the structure form the mere recitation of function and minimal structure is highly unlikely. In the latter case, disclosure of function alone is little more than a wish for possession; it does not satisfy the written description requirement. *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566, 43 U.S.P.Q.2d 1398, 1404, 1406

(Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998). *In re Wilder*, 736 F.2d 1516, 1521, 222 U.S.P.Q. 369, 372-3 (Fed. Cir. 1984). Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention.

The disclosure describes the isolation and characterization of a novel HIV-1 (originally termed the lymphadenopathy-associated virus or retrovirus) proviral molecular clone. The complete nucleotide sequence of this clone was ascertained and potential open reading frames identified. Under the summary of the invention it was stated that the present invention is directed toward "providing polypeptides containing sequences in common with polypeptides encoded by the LAV genomic RNA", to provide a "means for the detection of proteins related to LAV virus ... or, to the contrary, for the detection of antibodies against the LAV virus or proteins related therewith", and "providing immunogenic polypeptides". Under a detailed description of preferred embodiments the cloning strategy was provided, the complete nucleotide sequence of the clone was set forth, and the putative open reading frames gag, pol, env, ORF-Q, ORF-R, and ORFs-1-5 identified. While the disclosure mentions that these polypeptides can be utilized in the production of antibodies, **there is no indication anywhere that isolated and purified immunological complexes were ever contemplated or prepared.** Thus, the skilled artisan would reasonably conclude that applicants were not in possession of the claimed invention at the time of filing and that the rejection is proper.

Applicants traverse and again submit that a working embodiment is not required to have possession of the claimed invention. This argument is clearly not persuasive for the reasons set forth in the

rejection *supra* and as further elaborated herein. The legal requirements vis-à-vis the written description requirement have already been discussed above. The disclosure simply does **not** describe the preparation, purification, and use of a single immune complex involving the antigen and antibody of interest. The disclosure does **not** teach the skilled artisan how to even use such complexes. Accordingly, the rejection is proper and hereby maintained.

Finality of Office Action

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). **A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.**

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 9:30 AM to 7:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, Laurie Scheiner or James Housel, can be reached at (571) 272-0910 or (571) 272-0902, respectively. Direct general inquiries to the Technology Center 1600 receptionist at (571) 272-1600.

Formal communications may be submitted through the official

facsimile number which is (703) 872-9306. Hand-carried formal communications should be directed toward the customer window located in Crystal Plaza Two, 2011 South Clark Place, Arlington, VA. Applicants are directed toward the O.G. Notice for further guidance. 1280 O.G. 681. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Respectfully,

Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

29 March, 2004

LAURIE SCHEINER
PRIMARY EXAMINER

LAURIE SCHEINER
PRIMARY EXAMINER